

Patent

U.S. Ser. No.: 10/054,638

Response to the Office Action mailed 4 September 2008

Remarks

In response to the Office Action mailed 4 September 2008 the applicant herein submits the following amendments and remarks.

The applicant provides the following submissions with this communication: 1) applicant's facsimile cover page; 2) Transmittal Form (PTO/SB/21), 3) Certificate of Transmission (PTO/SB/97); 4) Petition for 3 Month Extension of Time under 37 C.F.R. §1.136(a) (PTO/SB/22); and 5) the applicant's substantive Amendment and Response (9 pages).

The Office Action set a three-month Shortened Statutory Period for reply extendable until 4 December 2008 under 37 C.F.R. §1.136(a) for submission of a responsive communication. Applicant's response is timely in view of the three (3) month Petition for Extension and payment of extension fees pursuant to 37 C.F.R. §1.17(a)(3). The applicant authorizes the Commissioner to charge, or credit any overpayment, associated/necessary with this communication to U.S.P.T.O. Deposit Account No.: 50-0244.

Claims 18-36, 46, and 48-51 are currently pending. The applicant has amended claim 18 in order to advance the prosecution and his business interests without acquiescing to the Examiner's arguments and while reserving the right to prosecute claims directed to any canceled, amended, or original subject matter in the future. The claim amendments are fully supported by the specification as originally filed and do not add new matter. Furthermore, the applicant has canceled claims 19-36, 46, and 48-51 without prejudice for like reasons and while reserving the right to prosecute the original or similar claims in the future.

In view of the applicant's last communication submitted on 12 June 2008 the Examiner withdrew/deemed moot the following pending rejections:

1. The objection to the Specification as containing New Matter (Office Action ¶3);
2. The new matter rejection of claims 56 and 57 (Office Action ¶5);
3. The obviousness rejection of claims 56 and 57 over Costantino *et al.*, (Vaccine, 10:691-698 (1992) in view of McMaster (U.S. 6,146,902), Chong *et al.*, (WO 99/42130), Lingappa *et al.*, (Vaccine, 19:4566-4575, August 2001), Perkins *et al.*, (J. Amer. Med. Assoc., 283(21):2842-2843, 7 June 2000) and Morley *et al.* (Vaccine, 20:666-687, 12 December 2001) (Office Action ¶6);
4. The new matter rejection of claims 18, 19-36, 46, and 48-51 (Office Action ¶7);

Patent

U.S. Ser. No.: 10/054,638

Response to the Office Action mailed 4 September 2008

5. The indefiniteness rejection of claim 22 (Office Action ¶8);
6. The indefiniteness rejection of claim 35 (Office Action ¶9);
7. The indefiniteness rejection of claim 48 (Office Action ¶10);
8. The indefiniteness rejection of claims 23-25, 36, 49, and 50 (Office Action ¶11); and
9. The obviousness rejection of claims 18-36, 46, and 48-51 over Costantino *et al.*, in view of McMaster, Chong *et al.*, Lingappa *et al.*, Perkins *et al.*, and Morley *et al.* (Office Action ¶12).

However, all of the pending claims currently stand rejected in the 4 September 2008 Office Action as follows:

1. Claims 18-33 are provisionally rejected under the non-statutory doctrine of obviousness type double patenting over co-pending application Ser. No.: 11/232,160 (Office Action ¶13);
2. Claim 18 stands rejected as allegedly containing new matter (Office Action ¶15);
3. Claims 18-22, 24-29, 31 and 32 stand rejected as allegedly being anticipated pursuant to 35 U.S.C. §102(b) under Beuvery *et al.*, (Infect. Immun., 41:609-617 [1983]) (Office Action ¶17);
4. Claims 34-36, 46, and 48 stand rejected as allegedly being obvious pursuant to 35 U.S.C. §103(a) under Beuvery *et al.*, in view of Fusco *et al.*, (Exprt. Opin. Investig. Drugs, 7:245-252 [1998]) (Office Action ¶19);
5. Claim 33 stands rejected as allegedly being obvious under Beuvery *et al.*, and McMaster in view of Perkins *et al.*, (J. Amer. Med. Assoc., 283(21):2842-2843, [2000]) (Office Action ¶20);
6. Claim 51 stands rejected as allegedly being obvious under Beuvery *et al.*, and McMaster (Office Action ¶21); and
7. Claims 49 and 50 stand rejected as allegedly being obvious under Beuvery *et al.*, in view of Fusco *et al.*, and Costantino *et al.*, (vaccine, 10:691-698 [1992]) (Office Action ¶22).

The amendments and remarks submitted herein are intended to be responsive to the Examiner's concerns, to advance the prosecution of the present application, and to place the

Patent

U.S. Ser. No.: 10/054,638

Response to the Office Action mailed 4 September 2008

application in condition for immediate allowance. Reexamination and reconsideration of the pending claims as amended herein is respectfully requested.

General Statements in the 4 September 2008 Office Action Requiring Clarification

Several statements made by the Examiner in the instant Office Action that are not specifically directed to particular rejections nonetheless require clarification.

First, applicant cited the Gizurarson reference and described its evidential applicability to unpredictability in the field of vaccine development back in 3 April 2006 Amendment and Response. As to applicant's alleged acknowledgement and acceptance of the Examiner's subsequent rebuttal, the record shows that the applicant has never acquiesced to the Examiner's position. Applicant's 20 September 2007 Response provides the following:

Applicant has repeatedly provided evidence of the unpredictability of the vaccine art. The Gizurarson paper was brought to the Examiner's attention to show that vaccinology is often an unpredictable art. This general point is likewise demonstrated in the Lindberg paper discussed above. [Applicant] submitted the Gizurarson paper to highlight that one skilled in the art would appreciate that vaccinology is generally unpredictable. The paper shows that even combinations of antigens which might be obvious to try are often not efficacious, only marginally efficacious, and in some instances even produce unexpected deleterious effects. The [applicant] is conscious of the current claim elements and also of the particulars of the Gizurarson paper.

(20 September 2007 Response and Amendment, p. 17). The next paper received by the applicant the 12 December 2007 Office Action was silent in response to the above quoted statement and was devoid of any surrebuttal. Accordingly, applicant respectfully submits that as of the 12 December 2007 Office Action, his remarks concerning the Gizurarson paper were accepted by the Office.

Second, the Examiner states that: "The alleged lack of success and the unpredictability of combining several components in a vaccine were addressed. In particular, the prior art reference of Tai *et al.* was cited, which demonstrated, with particular reference to a combined multivalent meningococcal glycoconjugate vaccine, the predictable efficacy and success.." (Office Action ¶14). Applicant respectfully submits the teachings of Tai *et al.* are being impermissibly broadened by the Examiner as evidence for her assertion that no reasonable unpredictability surrounded the instantly claimed invention at the time of its discovery.

Patent

U.S. Ser. No.: 10/054,638

Response to the Office Action mailed 4 September 2008

The Tai *et al.* reference was first cited by the Examiner at ¶20 of the 12 December 2007 Office Action. To be clear, Tai *et al.* has never been applied alone or in combination with any other references in any obviousness rejection to date. In the Examiner's own words Tai *et al.* "taught a trivalent combination vaccine comprising individual meningococcal serogroup A, B and C conjugates and its preclinical evaluation in monkeys." (12 December 2007 Office Action ¶20). To date, there is no *N. meningitidis* serogroup B protein-capsular polysaccharide conjugate vaccine widely approved for use in humans. If there was no reasonable unpredictability surrounding the development of even a monovalent B serogroup protein-capsular polysaccharide conjugate for human administration, as argued by the Examiner, why hasn't the work of Tai *et al.* translated into a product efficacious in humans to satisfy the unmet medical need for a serogroup B *N. meningitidis* vaccine? Applicant proffers an explanation; in general there is considerable unpredictability in the field of vaccinology, and more particularly, there is unpredictability in the field of efficacious tetravalent protein-capsular polysaccharide conjugates directed to *N. meningitidis* for human administration as are instantly claimed.

Applicant has submitted numerous references describing serious issues related to the unpredictability in the development of meningococcal related vaccines and other protein-capsular polysaccharide conjugates directed to other pathogens. Applicant has also provided evidence concerning secondary factors demonstrating the patentability of the various claimed embodiments of the present invention. These remarks are reiterated herein. Applicant specifically reserves the right to further discuss any portion of these remarks, the references already provided to the Office, or to make additional remarks and submit additional evidence concerning patentability in the future.

Third, the Examiner's stated "It is particularly noted that several years into prosecution Applicant has *failed* to disclose the reference of Beuvery *et al.* to the Office as required under § 1.56." (Office Action ¶14, emphasis in original). The applicant is familiar with the Title 37 §1.56. The Examiner is undoubtedly aware that there is no duty to undertake a search for potential prior art. Applicants have a statutory duty to provide the Office with information "known" to them. Similarly, applicant notes that the Examiner failed to cite and apply the Beuvery *et al.* and Fusco *et al.* references until this point in prosecution. MPEP §707.07(g), entitled "*Piecemeal Examination*," states that "Piecemeal examination should be avoided as

Patent

U.S. Ser. No.: 10/054,638

Response to the Office Action mailed 4 September 2008

much as possible. The examiner ordinarily should reject each claim on all valid grounds available, avoiding, however, undue multiplication of references. (See MPEP §904.03.).” In turn, MPEP §904.03, entitled “*Conducting the Search*,” states, in pertinent part, that “It is a prerequisite to a speedy and just determination of the issues involved in the examination of an application that a careful and comprehensive search, commensurate with the limitations appearing in the most detailed claims in the case, be made in preparing the first action on the merits so that the second action on the merits can be made final or the application allowed with no further searching other than to update the original search.”

Rejection 1: The Provisional Obviousness Type**Double Patenting Rejection of Claims 18-33**

Claims 18-33 are provisionally rejected under the non-statutory doctrine of obviousness type double patenting over co-pending application Ser. No.: 11/232,160. (Office Action ¶13). Claim 56 of the 11/232,160 application is no longer pending. Thus this rejection is moot.

The 11/232,160 application nevertheless formed the basis of and was incorporated by reference in its entirety into two recently filed Divisional applications. Applicant respectfully submits instant claim 18 and the claims of the aforementioned Divisional applications are free of the alleged obviousness type double patenting issues mentioned above.

Rejection 2: Alleged New Matter in Claim 18

Claim 18 stands rejected as allegedly containing new subject matter. (Office Action ¶15). The Examiner’s arguments can be summarized as that the terms: 1) “purified,” 2) “human,” and 3) “at least one of said polysaccharides” allegedly each add new matter. Applicant respectfully disagrees with the Examiner’s arguments. First, in regard to the term “purified,” without acquiescing to the Examiner’s arguments, applicant has removed the term “purified” from line 2 of pending claim 18, despite ample support in the Specification and the obvious common knowledge among those skilled in the art that medicinal compositions intended for administration to humans are invariable purified. Second, in regard to the term “human,” as was pointed out in the applicant’s last communication, Specification ¶¶0078-0091 describe the successful administration of combinations of the inventive compositions to “mice, rats and

Patent

U.S. Ser. No.: 10/054,638

Response to the Office Action mailed 4 September 2008

rabbits" (Specification ¶¶ 0078-0081) and humans (Specification ¶¶ 0082-0091). Applicant is perplexed as to why the Examiner maintains that the term "human" adds new matter to the instant claims. Third, in regard to the term "at least one of said polysaccharides," the Examiner's argument is moot in view of the abovementioned amendment to claim 18. MPEP §2163(I)(B) acknowledges that the specification provides support for all that it expressly, implicitly, or inherently teaches. The instant claims do not add new matter that was not previously disclosed. Applicant requests withdrawal of this rejection.

Rejection 3: Alleged Anticipation of Claims 18-22, 24-29, 31 and 32

Claims 18-22, 24-29, 31 and 32 are said to be anticipated by Beuvery *et al.* This rejection is moot in regard to canceled claims 19-22, 24-29, 31 and 32.

The Examiner states that Beuvery *et al.* teaches an "a vaccine composition comprising a mixture of individually made conjugates of purified capsular polysaccharides of four different meningococcal serogroups, A, C, W-135 and Z, wherein each of the purified capsular polysaccharide is individually conjugated to the protein carrier, tetanus toxoid." (Office Action ¶17).

MPEP §2131 states "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)."

Instant claim 18 is directed, in pertinent part, to "An immunological composition comprising a combination of four distinct and separately made protein-capsular polysaccharide conjugates . . . the second conjugate comprises the purified *N. meningitidis* capsular polysaccharide of serogroup Y conjugated to a carrier protein" The rejection does not establish that Beuvery *et al.* teaches the instantly claimed immunological composition. As such, applicant respectfully requests that this rejection be withdrawn.

Rejections 4, 5, 6, and 7: The Obviousness Rejections

Claims 33-36, 46, and 48-51 all stand rejected under the various above-mentioned combinations of references. The rejections are moot in view of the cancellations made herein for

Patent

U.S. Ser. No.: 10/054,638

Response to the Office Action mailed 4 September 2008

other reasons unrelated to patentability. Accordingly the applicant does not acquiesce to these, or any other, rejections made in the instant Office Action and he specifically reserves the right to prosecute the original, or similar, claims in the future as well as to make additional remarks and present additional evidence, in any form allowed, that shows the patentability of the subject matter presented expressly, implicitly, or inherently in the specification.

In view of the remarks previously made of record and those presented herein, all pending rejections have been overcome. Applicant respectfully requests the application be moved to allowance without further delay or prejudice to his interests.

Respectfully submitted,

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